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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,533	05/24/2007	D.Glenn Purcell	47082-155USPX	9803
71331	7590	07/06/2009	EXAMINER	
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CHICAGO, IL 60606				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,533	Applicant(s) PURCELL, D.GLENN	
	Examiner SARAH A. SIMPSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 7-13** are rejected under 35 U.S.C. 102(b) as being anticipated by **Levin et al. (US 5,517,978)**.

Regarding claim 7, Levin discloses a method for damping a lancet, comprising providing a lancet with a main housing (5) having an internal surface enclosing a portion of a lancing mechanism, the lancing mechanism including a lancet holder (25) attached to a shaft (29) and a drive spring (37) surrounding a portion of the shaft, the drive spring being located between the lancet holder and the internal surface, the lancing mechanism being adapted to move between a resting position, a cocking position, and a puncture position (figs. 2-3); and a movable housing (47) adjacent the main housing, the movable housing being adapted to move from a resting position to a cocking position, the moveable housing having an internal surface enclosing a portion of the shaft of the lancing mechanism, the enclosed portion of the shaft having a retainer (43) and a secondary spring (45) surrounding at least a section of the shaft, the secondary spring being located between the retainer and the internal surface of the movable

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housing, wherein the secondary spring is adapted to move the movable housing from the cocking position to the resting position, the secondary spring being further adapted to move the lancing mechanism from the puncture position to the resting position; compressing the drive spring and the secondary spring by moving the movable housing away from the main housing to the cocking position (columns 2-3, lines 63-68, 1-2; wherein the secondary spring is automatically compressed by pulling back the sleeve); decompressing the secondary spring to move the movable housing from the cocking position to the resting position, adjacent the main housing (column 3, 2-4); actuating the drive spring to cause the lancet holder to move from the cocking position to the puncture position (column 2, lines 41-52); recompressing the secondary spring as the lancet holder moves from the cocking position to the puncture position; and decompressing the secondary spring to move the lancet holder from the puncture position to the resting position (column 2, lines 52-57).

Regarding claim 8, Levin discloses wherein there is an act of adjusting the spring ratio between the drive spring and the secondary spring to adjust a force applied to the lancet holder as it moves from the cocking position to the puncture position (column 2-3, lines 63-68, 1-13).

Regarding claims 9, Levin discloses wherein the drive spring is not attached to the lancet holder or the internal surface of the main housing (figs. 2, 3).

Regarding claims 10, Levin discloses wherein the secondary spring is not attached to the retainer of the shaft or the internal surface of the movable housing

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(column 2, lines 30-32; wherein the spring is attached between the retainer and housing, on collar 41).

Regarding claims 11, Levin discloses wherein neither the drive spring nor the secondary spring are attached to any component of the lancing mechanism (figs. 2, 3).

Regarding claims 12, Levin discloses wherein the secondary spring constant is less than the spring constant of the drive spring (column 2, lines 52-57; wherein if the secondary spring had a spring constant greater than the drive spring than the needle would spring out of the housing again, puncturing the site twice and leaving the device inoperable).

Regarding claim 13, Levin discloses the act of piercing the skin of a test subject with a lancet received by the lancet holder as the lancet holder moves from the cocking position to the puncture position (figs. 2, 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Levin et al. (US 5,517,978)** in view of **LeVaughn et al. (EP 0898936)**.

Regarding claims 1 and 7, Levin discloses a method for damping a lancet, comprising providing a lancet with a main housing (5) having an internal surface enclosing a portion of a lancing mechanism, the lancing mechanism including a lancet holder (25) attached to a shaft (29) and a drive spring (37) surrounding a portion of the shaft, the drive spring being located between the lancet holder and the internal surface, the lancing mechanism being adapted to move between a resting position, a cocking position, and a puncture position (figs. 2-3); and a movable housing (47) adjacent the main housing, the movable housing being adapted to move from a resting position to a cocking position, the moveable housing having an internal surface enclosing a portion of the shaft of the lancing mechanism, the enclosed portion of the shaft having a retainer (43) and a secondary spring (45) surrounding at least a section of the shaft, the secondary spring being located between the retainer and the internal surface of the movable housing, wherein the secondary spring is adapted to move the movable housing from the cocking position to the resting position, the secondary spring being further adapted to move the lancing mechanism from the puncture position to the resting position; compressing the drive spring and the secondary spring by moving the movable housing away from the main housing to the cocking position (columns 2-3,

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lines 63-68, 1-2; wherein the secondary spring is automatically compressed by pulling back the sleeve); decompressing the secondary spring to move the movable housing from the cocking position to the resting position, adjacent the main housing (column 3, 2-4); actuating the drive spring to cause the lancet holder to move from the cocking position to the puncture position (column 2, lines 41-52); recompressing the secondary spring as the lancet holder moves from the cocking position to the puncture position; and decompressing the secondary spring to move the lancet holder from the puncture position to the resting position (column 2, lines 52-57).

Levin fails to disclose wherein the movable housing is completely separated from the main housing when moved from the cocking position to the resting position.

However, LeVaughn teaches a lancing device with multiple springs and housings wherein the main housing (12) is separated from the movable housing (14) when in a cocked position (fig. 4).

Given the teachings of LeVaughn, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Levin by separating the main housing from the movable housing when moved from the cocking position to the resting position. It has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Further using a separate piece to connect the two housings as shown in LeVaughn would allow the user to easily identify when the device is in the cocked position as opposed to the resting position.

Regarding claims 2 and 12, Levin discloses wherein the secondary spring constant is less than the spring constant of the drive spring (column 2, lines 52-57;

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wherein if the secondary spring had a spring constant greater than the drive spring than the needle would spring out of the housing again, puncturing the site twice and leaving the device inoperable).

Regarding claims 3 and 9, Levin discloses wherein the drive spring is not attached to the lancet holder or the internal surface of the main housing (figs. 2, 3).

Regarding claims 4 and 10, Levin discloses wherein the secondary spring is not attached to the retainer of the shaft or the internal surface of the movable housing (column 2, lines 30-32; wherein the spring is attached between the retainer and housing, on collar 41).

Regarding claims 5 and 11, Levin discloses wherein neither the drive spring nor the secondary spring are attached to any component of the lancing mechanism (figs. 2, 3).

Regarding claim 6, Levin discloses wherein the secondary spring surrounds the entirety of the portion of the shaft enclosed within the movable housing (fig. 3).

Regarding claim 8, Levin discloses wherein there is an act of adjusting the spring ratio between the drive spring and the secondary spring to adjust a force applied to the lancet holder as it moves from the cocking position to the puncture position (column 2-3, lines 63-68, 1-13).

Regarding claims 9, Levin discloses wherein the drive spring is not attached to the lancet holder or the internal surface of the main housing (figs. 2, 3).

Regarding claim 13, Levin discloses the act of piercing the skin of a test subject with a lancet received by the lancet holder as the lancet holder moves from the cocking position to the puncture position (figs. 2, 3).

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments have been fully considered but they are not persuasive. The Applicant argues that the drive spring is not adjacent to and between the lancet holder and the internal surface at a first end of the main housing and that instead the plunger 21 is adjacent the spring. However, the Examiner would like to clarify that both the needle holder 25 and the plunger 21 of Levin are interpreted together to read on "the lancet holder" of the present application. Therefore, the drive spring 37 is adjacent to the lancet holder.

The Applicant also argues that the secondary spring is not located adjacent to and between the retainer and the internal surface of the movable housing at the first end of the movable housing and that instead the secondary spring of Levin is located between flange 43 and abutment 49 positioned in a central portion of the outer sleeve 47. However, the claim requires a movable housing having a first end adjacent the first end of the main housing. Clearly, as shown in Figures 2 and 3 of Levin, abutments 49 of the movable housing 47 are adjacent the first end of the movable housing 5;

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therefore, the abutments 49 are interpreted as a first end of the movable housing. The spring 45 also engages the top of the abutment 49 as shown in Figure 3; therefore, the spring is between the retainer 43 and an internal surface of the movable housing at the first end of the movable housing.

With respect to claim 7, the Applicant argues that Levin fails to disclose "moving the movable housing away from the main housing to the cocking position" because the main housing and the movable housing are not separated from each other. However, moving two objects away from each other does not require the objects to be completely separated. For example, when stretching a spring the ends are moved further away from each other when in a cocked position and closer to each other in a resting position. Therefore, claim 7 does not require the two housings to be separated from each other when moved apart from each other.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/3/09